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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/049,142 | 02/05/2002 | Nicholas Maughan Clayton | PG3749USW | 7895 |
| 23347 | 7590 | 06/17/2004 | EXAMINER | |
| DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY GLAXOSMITHKLINE FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398 | | | SHARAREH, SHAHNAM J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/049,142 | Applicant(s) CLAYTON ET AL. | |
| | Examiner Shahnam Sharareh | Art Unit 1617 | |
| | | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 18 February 2004.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 5, 6, 14, 15 and 19-37 is/are rejected.

7) ☒ Claim(s) 30-37 is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 2/18/2004.

4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on February 18, 2004 has been entered. Claims 5-6, 14-15, 19-37 are pending.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5-6, 14-15, 19-29 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for EP 4 ligands and or antagonists represented and enumerated on pages 3-8 of the specification, does not reasonably provide enablement for any and all EP4 ligands and/or antagonists for the reasons of record.

Applicant first argues that the term "EP4 ligands" are well known class of compounds and are defined in the art as such class of compound, which binds to the EP4 receptors. Applicant first argues that the specification has described an assay for EP4 receptor binding ability at page 9-10. Arguments at page 7, para 3-page 8, para 2. Accordingly, Applicant appears to conclude that given the state of the art and methods for identifying the same, the compounds in such class of compounds can be recognized in the art their definition; structure and chemical characteristics are well ascertainable (see).

In response to such line of argument, Examiner draws Applicant's Attention to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein

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employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty." Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outline goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate."

Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provides those elements required to practice the inventions; nor "inform the public during the life of the patent of the limits of the monopoly asserted." *General Electric Company v. Wabash Appliance Corporation et supra*, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Applicant then draws analogies to the *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and argued that the instant screening methods for determining if compounds are EP4 receptor ligands is disclosed at pages 8-10 and following the *Wands* decision, the instant specification is adequately enabling the entire scope of the class EP 4 ligands.

In response Examiner states the rejection does not dispute whether the term EP4 ligand is understood in the art. Rather, does the specification adequately enable one of ordinary skill in the art to practice the entire scope of presented claims using the entire class of EP4 receptor ligands. In contrary to Applicant's arguments, Examiner states that in *Wands*, the Applicants presented data in a declaration that the court construed as adequate with respect to the scope of enablement rejection.

Here, neither the specification shows enabling methodologies for treating neuropathic pain or colon cancer, etc.. when EP4 receptor ligands are employed; nor, is there any declaration provided to reasonably provide a pattern or subgenus with the claimed compounds EP4 receptors. The state of prior art does not indicate methods of treating colon cancer, HIV or neuropathic pain with EP4 receptor ligands. Further, unlike in *Wands*, the declaration provided here is directed to only one compound which by no way represents the entire class of EP ligands. Therefore, Applicant's arguments were not found persuasive and thus claims stand rejected.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 are directed to 4-(4,9-diethoxy-1-oxo-1,3-dihydro-2H-benzo[f]isoindol-2-yl)phenyl]acetic acid and derivatives thereof. The specification fails to provide to which

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derivatives is applicant referring. Accordingly, the recitation is unclear and fails to describe the metes and bounds of the claims.

Claim Rejections - 35 USC § 103

Claims 22-24, 27-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Foord in view of Katzung.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant has provided a declaration under 37 CFR 1.132 to show unexpected synergistic effects when combining an EP4 ligand and a cox-2 inhibitor. (see Arguments at page 7).

However, the Declaration under 37 CFR 1.132 filed February 18, 2004 is insufficient to overcome the rejection of claims 22-24, 27-29 based upon a rejection under 35 U.S.C. 103(a) over Foord in view of Katzung as set forth in the last Office action.

First, the declaration is not commensurate with the scope of the pending claims and does not represent adequate species from each class of compound to represent sufficient evidence of unexpected results for the claimed combination. Second, the declaration is directed to a dose and time sensitive synergy between the compounds 4-(4,9-diethoxy-1-oxo-1,3-dihydro-2H-benzo[f]isoindol-2-yl)phenyl]acetic acid and 2-(4-Ethoxyphenyl) 3-(4-methanesulfonyl-phenyl)-pyrazolo[1,5-b] pyridazine. There is no expectation whether other EP4 ligands and Cox-2 inhibitors are able to provide the same synergistic effects. Furthermore, the claimed compound of the compositions of claim 22 and 27 will provide their therapeutic effects simultaneously, not, as showed on

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the declaration, one hour apart from each other. Therefore, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

Claim Objections

Claims 30-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 30-37 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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